

## REMARKS

Claims 10-15 remain pending. Reconsideration of the application is respectfully requested.

Claim 10 was again rejected under 35 U.S.C. § 102(b) as anticipated by Wang (USPN 5,348,538). The Examiner argues that the stretching step of Wang et al does not preclude the tube from being annealed. It is however noted that if annealing were in fact to occur during the stretching of the tube as per the Examiner's suggestion, the tube would in fact be annealed **while** it is being longitudinally **expanded**. In stark contrast thereto, the rejected claims unequivocally call for the tube to be annealed "**prior to any expansion of the tube.**" Moreover, the only express teaching of an annealing step is that it is to be performed at the conclusion of the manufacturing process. At col 7, line 47-61 it is disclosed that the process comprises the steps of: "extruding,...blow molding,... and annealing" while the disclosure at col 7, line 47-61 makes it clear that annealing is to be performed after the expansion(s) "the **final** process that the assembled balloon catheter must undergo is the annealing technique." No mention of another annealing step is made. In view of the fact that anticipation by a reference requires a teaching of the step that is being claimed rather than merely that the step is "not precluded" thereby, it is respectfully submitted that anticipation is clearly avoided.

It is additionally to be noted that the reference actually teaches away from any annealing of the tube **prior** to its longitudinal or even its radial expansion with the teaching at col 9, lines 32-34 wherein it is expressly stated that it is preferred that the balloon be molded "**soon** after the tube has been **extruded**, to insure that conditions of the tube, such as moisture content remain acceptable." In view of the fact that an annealing process is inherently time consuming (e.g. claim 11 – "16-24 hours"), "soon after" would connote the absence of an annealing step. Finally, the cited reference fails to teach a second heating step that is performed at a temperature of **not less** than the temperature at which the material is radially expanded. The reference describes a process wherein the expansion is performed at a temperature of 95C (col. 10, line 65 to col. 11,

line 9) and a subsequent annealing at 25-100C, **preferably** 65-80C and thereby fails to teach that the annealing temperature **must** be less than the expansion temperature. As such, it is respectfully submitted that the cited reference teaches a markedly different process for manufacturing a non-compliant balloon using a block copolymer and as consequence, obviousness is effectively avoided.

Claims 11-15 were rejected under 35 U.S.C. § 103(a) as obvious over Wang. In light of the non-obviousness of underlying independent claim 10 as was argued above, it is respectfully submitted that all claims depending therefrom similarly avoid obviousness.

In light of the above remarks, applicants earnestly believe the application to now be in condition for allowance and respectfully request that it be passed to issue.

The commissioner is authorized to charge any deficiencies in fees or credit any overpayments to our Deposit Account No. 06-2425.

Respectfully submitted,

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